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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,838	04/20/2004	Stephanie M. Kladakis	022956-0261	5281
21125 7590 03/19/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
WOODWARD, CHERIE MICHELLE				
ART UNIT		PAPER NUMBER		
1647				
NOTIFICATION DATE		DELIVERY MODE		
03/19/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/828,838

**Applicant(s)**

KLADAKIS ET AL.

**Examiner**

CHERIE M. WOODWARD

**Art Unit**

1647

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 27 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-8, 10-14, 16-27 and 32-34.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

Cherie M. Woodward  
Examiner  
Art Unit: 1647

/Gary B. Nickol/  
SPE, Art Unit 1646

Continuation of 3. NOTE: Applicant's amendments to claims 1 and 19 constitute new matter. Applicant argues that paragraph 48 of the patent application publication (US 20050232967) provides support for Applicant's amendments to claims 1 and 19, which recite a "density greater than about 120 mg/cc" (see Remarks, p. 6, third paragraph). Paragraph 48 states that the "density is in the range of about 120mg/cc to 360mg/cc" (last sentence of paragraph 48). Applicant's amendment does not limit the upper end of the disclosed range and as such, the scope of the range, as claimed, far exceeds the range set forth in the specification. This constitutes new matter.

With regard to Applicant's arguments set forth in the Remarks filed 2/27/2008, Applicant's amendments have not overcome the rejections under 35 USC 112, second paragraph (see Remarks, p. 6, fourth paragraph). The rejection under 35 USC 112, second paragraph would be overcome if Applicant were to recite the density range as stated in paragraph 48 of the patent application publication.

With regard to Applicant's arguments pursuant to the rejection under 35 USC 103, Applicant argues that the prior art references do not teach or suggest a nonwoven material that has the claimed density (Remarks, p. 7, first full paragraph). Applicant argues that the examiner's citation of the common use of the tradenamed product, VICRYL, is not applicable because VICRYL is not a "nonwoven polymer" (Remarks, p. 7, first full paragraph). Applicant's argument has been fully considered, but is not persuasive. Applicant has apparently misunderstood the examiner's statement on page 4 of the Office Action mailed 12/31/2007. The examiner's statement regarding VICRYL was not made to suggest that VICRYL was anything more than a PLA/PGA copolymer. Rather, the examiner was merely pointing out that the nonwoven compositions comprising VICRYL and PDS (recited on page 9, paragraph 54 of the specification) showed a higher density than the ones exemplified on page 20 (paragraph 88) of the specification. Although Bowman et al., (US 20020127265) does not recite the density of their nonwoven scaffolds in units of mg/cc, the '265 publication provides sufficient evidence that such density is a testable physical property. The '265 publication states that "[t]he density or 'openness' of a mesh material can be evaluated using a digital photocamera interfaced with a computer. In one evaluation, the density of the mesh was determined using a Nikon SMZ-U Zoom with a Sony digital photocamera DKC-5000 interfaced with an IBM 300PL computer" and "Image-Pro Plus 4.0 software in order to determine the mesh density. Once a digital image was captured by the software, the image was thresholded such that the area accounting for the empty spaces in the mesh could be subtracted from the total area of the image. The mesh density was taken to be the percentage of the remaining digital image. Implants with the most desirable mechanical properties were found to be those with a mesh density in the range of about 12 to 80% and more preferably about 45 to 80%" (paragraph 65). As previously stated of record, the Patent Office does not have the facilities to determine whether the scaffolds taught by the '265 publication or by WO 01/85226 have densities that meet the limitations of the instant claims (see In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (CCPA 1972) and Ex parte Gray, 10 USPQ2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.). Applicant is in the best position to provide additional data in this regard.

With regard to Applicant's argument that the '265 publication does not teach a scaffold having a modulus of elasticity greater than about 1.5MPa, and that the examiner has not provided the required rationale or evidence tending to show that the claimed properties would have been inherent in the scaffold of the '265 publication (see Remarks, p. 7, last paragraph), Applicant is directed to paragraph 31 of the '265 publication which recites "[i]n addition to these elongation and modulus properties, suitable elastomers should also have a tensile strength greater than about 500 psi, preferably greater than about 1,000 psi, and a tear strength of greater than about 50 lbs/inch, preferably greater than about 80 lbs/inch." Because the modulus of elasticity is the ratio of stress to strain, the '265 publication provides sufficient evidence to suggest that, absent evidence to the contrary, the scaffolds taught therein will have a modulus of elasticity greater than about 1.5MPa, based on the stress and strain requirements set forth in the '265 publication.

With regard to Applicant's argument that the examiner's reliance on Boland is misplaced (Remarks, p. 8, second paragraph), Applicant's argument is not persuasive. Boland was only cited as an exemplary reference for background on electrospinning (see Office Action of 5/4/2007, p. 8, last paragraph). One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With regard to Applicant's argument regarding the provisional obviousness type double patenting rejection (Remarks, p. 8, last paragraph), the claims are not in condition for allowance and as such, Applicant's argument is moot.